



## General

### Guideline Title

Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of Neurological Surgeons systematic review and evidence-based guideline.

### Bibliographic Source(s)

Sweet JA, Mitchell LS, Narouze S, Sharan AD, Falowski SM, Schwalb JM, Machado A, Rosenow JM, Petersen EA, Hayek SM, Arle JE, Pilitsis JG. Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of Neurological Surgeons systematic review and evidence-based guideline. *Neurosurgery*. 2015 Sep;77(3):332â€“41. [23 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Regulatory Alert

### FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [December 14, 2016 – General anesthetic and sedation drugs](#) : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

## Recommendations

### Major Recommendations

The rating scheme used for strength of the evidence (Class I-III) and the levels of recommendations (Level I-III) are defined at the end of the "Major Recommendations" field.

## Summary of Recommendations

The data from a recent systematic review of the literature supports the use of occipital nerve stimulation (ONS) as a treatment option for patients with medically refractory occipital neuralgia (ON) (Level III recommendation). A summary of the recommendation for the use of ONS for the treatment of ON can be found in Table 4 in the original guideline document.

## Definitions

### Levels of Evidence for Primary Research Question<sup>1</sup>

	<b>Therapeutic Studies: Investigating the Results of Treatment</b>	<b>Prognostic Studies: Investigating the Effect of a Patient Characteristic on the Outcome of Disease</b>	<b>Diagnostic Studies: Investigating a Diagnostic Test</b>	<b>Economic and Decision Analyses: Developing an Economic or Decision Model</b>
<b>Class I</b>	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic review<sup>2</sup> of Class I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq 80\%</math> follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>
<b>Class II</b>	<ul style="list-style-type: none"> <li>Lesser quality RCT (e.g., <math>&lt;80\%</math> follow-up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Class II studies or Class I studies with inconsistent results</li> <li>Case control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Class II studies</li> </ul>	<ul style="list-style-type: none"> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <math>&lt;80\%</math> follow-up)</li> <li>Systematic review<sup>2</sup> of Class II studies</li> <li>Case control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Class II studies</li> <li>Study of nonconsecutive patients; without consistently applied "gold" standard</li> <li>Systematic review<sup>2</sup> of Class III studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>
<b>Class III</b>	<ul style="list-style-type: none"> <li>Case series<sup>8</sup></li> <li>Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>Case series</li> <li>Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>Case control study</li> <li>Poor reference standard</li> <li>Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>Analyses with no sensitivity analyses</li> <li>Expert opinion</li> </ul>

RCT = randomized controlled trial

<sup>1</sup>A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>2</sup>A combination of results from two or more prior studies.

<sup>3</sup>Studies provided consistent results.

<sup>4</sup>Study was started before the first patient enrolled.

<sup>5</sup>Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

<sup>6</sup>The study was started after the first patient enrolled.

<sup>7</sup>Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

<sup>8</sup>Patients treated one way with no comparison group of patients treated in another way.

## American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Classification of Evidence on Therapeutic Effectiveness and Levels of Recommendation

<b>Class I evidence: Level I recommendation</b>	Evidence from $\geq 1$ well-designed, randomized, controlled clinical trials, including overviews of such trials
<b>Class II evidence: Level II recommendation</b>	Evidence from $\geq 1$ well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well designed randomized, controlled trials
<b>Class III evidence: Level III recommendation</b>	Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized, controlled trials

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

Occipital neuralgia (ON)

## Guideline Category

Management

Treatment

## Clinical Specialty

Neurological Surgery

Neurology

## Intended Users

Physicians

## Guideline Objective(s)

To systematically review the medical literature and provide recommendations for the use of occipital nerve stimulation (ONS) for the treatment of patients with medically refractory occipital neuralgia (ON).

Note: The Task Force restricted their analysis to the use of ONS for the treatment of ON. This technique has also been used for the treatment of other disorders, most prominently

migraine headaches. Given the heterogeneity of that diagnosis, they did not include it in this set of guidelines.

## Target Population

Patients with medically refractory occipital neuralgia (ON)

## Interventions and Practices Considered

Occipital nerve stimulation (ONS)

## Major Outcomes Considered

- Change in visual analog scale (VAS)
- Change in short-form McGill Pain Questionnaire
- Improvement in the Pain Disability Index score
- Symptom improvement
- Use of analgesic medication

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

#### Literature Search

A systematic literature search was undertaken to address the primary question: Is occipital nerve stimulation (ONS) an effective treatment for occipital neuralgia (ON)? Using the PubMed database, a search of articles published between 1966 and April 2014 was conducted using the following text word combinations: "occipital nerve stimulation and occipital neuralgia" or "electrical stimulation and occipital neuralgia" or "neuromodulation and occipital neuralgia" or "peripheral neurostimulation and occipital neuralgia" or "occipital nerve stimulation and cervicogenic headache" or "neuromodulation and cervicogenic headache" or "occipital nerve stimulation and C2 headache." These searches generated lists of 50, 38, 21, 11, 11, 6, and 10 articles, respectively. Each article was reviewed by at least 2 independent reviewers to determine whether they met the qualifications for full text review. Cochrane Library was also searched with a combination of the keywords used to search PubMed (see the Supplemental Digital Content document [see the "Availability of Companion Documents" field]); however, no unique results were located.

The Task Force performed a secondary literature search to see whether there were interventions that predict response to ONS in ON. Using the PubMed database up to June 2014, the following text words were combined for the search: "occipital nerve block and occipital nerve stimulation" or "occipital nerve block and occipital nerve stimulation and occipital neuralgia" or "occipital nerve blocks predictive of occipital nerve stimulation" or "response to occipital nerve stimulation and occipital neuralgia" or "occipital nerve block and stimulation response" or "occipital nerve block predictive of peripheral nerve stimulation" or "predictors of occipital peripheral nerve stimulation" or "predictors of peripheral nerve stimulation and occipital neuralgia" or "occipital nerve injections and occipital neuralgia" or "occipital nerve injection and occipital nerve stimulation." A total of 89 unique articles were found. Only 8 articles looked at an intervention in patients with ON and none of these articles included patients with ONS. Cochrane Library was also searched with a combination of the keywords used to search PubMed (see the Supplemental Digital Content document); however, no unique results were located.

#### Article Inclusion Criteria

Inclusion criteria were as follows: (1) clinical series must have a minimum of 3 patients undergoing ONS for treatment of medically refractory ON, (2) clinical series must have a minimum of 2 months postoperative follow-up from ONS implantation, and (3) series that enrolled mixed patient populations were included only if they reported separate results for the target ON population. The results of the target population were the only

results considered as evidence to support the recommendations. A total of 81 unique articles were found. Clinical series containing 3 or more patients with a minimum follow-up of 2 months were pooled for analysis.

Of the 81 articles, 72 studies were excluded for the following reasons: 1 was an abstract only, 2 were animal studies, 4 were not in English, 11 were case reports with a single patient, 6 were meta-analyses, 17 were review articles, 30 addressed either an alternative disease process (e.g., trigeminal neuralgia or chronic migraines) or a treatment option other than ONS (e.g., occipital nerve blocks), and 1 was a mixed population of patients that did not separate the results for each population group. Ultimately, 9 original articles were selected and retrieved for analysis. These articles are listed in the Evidentiary Table (see Table 2 in the original guideline document).

A secondary analysis of the 9 selected articles was also performed in an effort to address any significant anatomic or technical considerations for ONS implantation. All of the 9 articles made at least 1 reference to an anatomic and/or technical aspect of ONS, which are also shown in Table 2 of the original guideline document.

## Number of Source Documents

Nine primary articles addressed the efficacy of occipital nerve stimulation (ONS) for the specific treatment of occipital neuralgia (ON) (see Table 2 in the original guideline document). All articles provided Class III Level evidence. Three articles were prospective case series without a control group and as such were graded as Class III. One article was a cohort study in which each patient served as his or her own control. However, the data were collected and reviewed retrospectively, making this Class III evidence as well. Four articles were retrospective case series, thus accounting for their classification. Finally, 1 article did not specify whether it was prospective or retrospective, but, given it was a small case series, it was also graded as Class III.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Levels of Evidence for Primary Research Question<sup>1</sup>

	<b>Therapeutic Studies: Investigating the Results of Treatment</b>	<b>Prognostic Studies: Investigating the Effect of a Patient Characteristic on the Outcome of Disease</b>	<b>Diagnostic Studies: Investigating a Diagnostic Test</b>	<b>Economic and Decision Analyses: Developing an Economic or Decision Model</b>
<b>Class I</b>	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic review<sup>2</sup> of Class I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with <math>\geq 80\%</math> follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Class I studies</li> </ul>
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	<b>Therapeutic Studies:</b> Investigating the Results of Treatment <ul style="list-style-type: none"> <li>• Case control study<sup>7</sup></li> <li>• Retrospective<sup>6</sup> comparative study<sup>5</sup></li> </ul>	<b>Prognostic Studies:</b> Investigating the Effect of a Patient Characteristic on the Outcome of Disease <ul style="list-style-type: none"> <li>• Systematic review<sup>2</sup> of Class II studies<sup>3</sup></li> </ul>	<b>Diagnostic Studies:</b> Investigating a Diagnostic Test <ul style="list-style-type: none"> <li>• nonconsecutive patients; without consistently applied "gold" standard</li> <li>• Systematic review<sup>2</sup> of Class III studies</li> </ul>	<b>Economic and Decision Analyses:</b> • Developing an Economic or Decision Model <ul style="list-style-type: none"> <li>• Review<sup>2</sup> of Level III studies</li> <li>• Analyses based on limited alternatives and costs; and poor estimates</li> <li>• Systematic review<sup>2</sup> of Level III studies</li> </ul>
<b>Class III</b>	<ul style="list-style-type: none"> <li>• Case series<sup>8</sup></li> <li>• Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>• Case series</li> <li>• Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>• Case control study</li> <li>• Poor reference standard</li> <li>• Expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>• Analyses with no sensitivity analyses</li> <li>• Expert opinion</li> </ul>

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<sup>8</sup> Patients treated one way with no comparison group of patients treated in another way.

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

### Grading Evidence

The strength of evidence of each article that underwent full text review was graded according to the criteria established by the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Joint Guidelines Committee (JGC). Each article was independently graded by multiple reviewers, and any conflicts between the reviewers' grading was resolved via discussion. The class of evidence (i.e., Class I, II, or III) assigned to each article was determined after review of the sample size, study design, follow-up, and outcome measures (see the "Rating Scheme for the Strength of the Evidence" field).

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

### Guideline Task Force

A multidisciplinary task force of volunteer neurosurgeons and pain management physicians comprised the Guidelines Task Force and were

responsible for the formation of these evidence-based guidelines.

#### Guideline Panel Consensus

The literature searches were performed by a single member of the group and distributed to the entire group for literature review, article selection, and the formation of the evidentiary table. Task Force subgroups were then established by topic. Information was compiled by that subgroup and then distributed to the entire group for review until a final consensus by means of group discussion, voting, and approval was achieved.

The Task Force implemented a modified structured voting technique to finalize and approve the recommendations and strength of recommendations presented in this review. If and when a disparity in opinions occurred, every effort was made to amend the guideline to adequately address each viewpoint until all members were in agreement. In the event that a unanimous decision could not be made, the question was posed to the Task Force as a whole, and the majority opinion was used. This method was agreed upon by all members of the Task Force.

#### Levels of Recommendations

The strength of clinical recommendations (i.e., Level I, II, or III) was linked to the level of evidence included to support the recommendation (see the "Rating Scheme for the Strength of the Recommendations field").

## Rating Scheme for the Strength of the Recommendations

#### American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Classification of Evidence on Therapeutic Effectiveness and Levels of Recommendation

<b>Class I evidence: Level I recommendation</b>	Evidence from $\geq 1$ well-designed, randomized, controlled clinical trials, including overviews of such trials
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<b>Class III evidence: Level III recommendation</b>	Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized, controlled trials

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

#### Practice Guideline Approval Process

The completed systematic review was distributed to the Joint Guidelines Committee (JGC) of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) for consideration of endorsement by the CNS Executive Committee and the AANS Board of Directors. JGC reviewers were permitted to critique the content and methodology used to create this systematic review. Any concerns of the JGC were addressed by the Task Force, and the document was resubmitted to the JGC for endorsement. In addition, these guidelines were independently submitted to the American Society of Regional Anesthesia and Pain Medicine and the American Interventional Headache Society for review and were approved for endorsement by these organizations. As such, support of these guidelines was also multidisciplinary in nature. Once this process was completed, the document was submitted for publication. This was editorially independent of the funding agencies of the CNS Executive Committee and the AANS/CNS Joint Pain Section Executive Committee, whose involvement occurred after the approval of the



guidelines by the JGC and was limited to acceptance versus rejection of endorsement of the work.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Occipital nerve stimulation (ONS) constitutes a promising therapy for medically refractory occipital neuralgia (ON) because it is reversible with minimal side effects and has shown continued efficacy with long-term follow-up.

### Potential Harms

- The major technical problem of occipital nerve stimulation (ONS) is lead migration, ranging in several prospective studies on ONS for the treatment of migraines from 13.9% to 24%.
- Complications of ONS from the 9 primary articles are summarized and shown in Table 3 in the original guideline document.

## Qualifying Statements

### Qualifying Statements

- The literature review and presented evidence-based guidelines were developed by a multidisciplinary group of physician volunteers. The purpose of these guidelines is to serve as an educational resource assessing the currently available scientific evidence pertaining to the use of occipital nerve stimulation (ONS) for the treatment of medically refractory occipital neuralgia (ON). The guidelines in this article are based on up-to-date information at the time of completion of this document. These guidelines are not intended to be a rigid protocol, and clinical interventions may vary according to a patient's needs. Clinical judgment should always take precedence in the treatment of patients. These guidelines are presented with the understanding that they are not meant to replace the individualized care and treatment of a specific patient by his or her physician(s). These guidelines may not be suitable in all situations or applicable to all patients with ON. Implementation of these guidelines should be done by a patient's managing physician(s) in accordance with each patient's individual circumstances and clinical needs.
- The primary limitation of this guideline is the current level of evidence available for the use of ONS specifically for the treatment of medically refractory ON. Although prospective, randomized, controlled trials and other well-designed studies demonstrating the effectiveness of ONS have been conducted, the patient populations evaluated in these studies were not specific to medically refractory ON patients. Prospective comparative studies are needed to fully determine the long-term utility of ONS for the treatment of ON. It will be difficult to conduct blinded trials of ONS because the therapy depends on the production of paresthesia detected by the patient in the painful region. The closest alternative is the use of subthreshold stimulation, but there are some who believe that even subthreshold stimulation can result in a therapeutic effect. Research also needs to be conducted into the optimal region for lead placement and the optimal lead type.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.



## Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

## Identifying Information and Availability

### Bibliographic Source(s)

Sweet JA, Mitchell LS, Narouze S, Sharan AD, Falowski SM, Schwalb JM, Machado A, Rosenow JM, Petersen EA, Hayek SM, Arle JE, Pilitsis JG. Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of Neurological Surgeons systematic review and evidence-based guideline. *Neurosurgery*. 2015 Sep;77(3):332-41. [23 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2015 Sep

### Guideline Developer(s)

Congress of Neurological Surgeons - Professional Association

### Source(s) of Funding

#### Sources of Support

This systematic review and evidence-based clinical practice guideline was funded exclusively by Congress of Neurological Surgeons (CNS) and the Joint Section on Pain of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS), who received no funding from outside commercial sources to directly support the development of this document unless otherwise stated in this section.

# Guideline Committee

Guideline Task Force

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

### Disclosures

Dr Machado has ownership interest and consulting agreements with Enspire, ATI, and Cardionomics. Dr Sharan has consulting relationships with Medtronic, has received grants and honoraria from St. Jude Medical, is a Director and has ownership interest in ICP and in ICVRX. Dr Petersen is a consultant for St. Jude Medical and Medtronic. Dr Hayek is a consultant for Boston Scientific, Flowonix, and Mallinckrodt. Dr Arle is a consultant for St. Jude Medical. Dr Rosenow is a consultant for Boston Scientific and the GLG Group. Dr Schwalb has received honoraria from Medtronic. Dr Pilitsis is a consultant for and has received grants from Medtronic, St. Jude Medical, and Boston Scientific, and is a recipient of an NIH grant. Dr Falowski has research grants from and is a consultant for Medtronic and St. Jude Medical. All other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article and related to occipital nerve stimulators.

## Guideline Endorser(s)

American Association of Neurological Surgeons - Medical Specialty Society

American Interventional Headache Society - Professional Association

American Society of Regional Anesthesia and Pain Medicine - Medical Specialty Society

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available in PDF and ePub for eBook devices from the [Neurosurgery Web site](#) .

## Availability of Companion Documents

The following are available:

- Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of Neurological Surgeons

systematic review and evidence-based guideline. Supplemental Digital Content. 2015 Sep. 1 p. Available from the [Neurosurgery Web site](#) .

- Guideline development methodology: endorsed by the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Guideline Committee. 2012 Feb. 12 p. Available from the [Congress of Neurological Surgeons Web site](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on November 19, 2015. The information was not verified by the guideline developer. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

## Copyright Statement

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## Disclaimer

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